

REMARKS:

- 1) Referring to item 10) of the Office Action Summary, the objection to the drawing has been overcome by the present claim amendment, as will be discussed below. Thus, there is no need to file corrected drawings.
- 2) Referring to section 9 on page 4 of the Office Action, the Examiner has referred to an additional reference, U. S. Patent 6,106,550 (Magovern et al.). This additional reference is, however, not listed on the Notice of References Cited (Form PTO-892) and was not enclosed with the Office Action. Since the Examiner apparently considered the Magovern et al. Patent, it is respectfully requested that this Patent should be listed on Form PTO-892, and a copy should be provided to the applicant.
- 3) The claims have been amended as follows.
 - Claims 9 to 23, 26, 28 and 30 have been canceled.
 - Claim 24 has been amended to incorporate the subject matter of prior claim 26.
 - Claim 27 has been amended to incorporate the subject matter of prior claim 28.
 - Claim 29 has been amended for proper dependency in view of the amendment of claim 27 and cancellation of claim 28.New claims 32 to 47 have been added. The new claims are supported by the subject matter of the original disclosure as shown in the following table, and do not introduce any new matter.

New Claims	32	33	34	35	36	37	38	39
Original Support	Cl. 9,10,11,12,16,26	Cl. 11	Cl. 12	Cl. 13	Cl. 14	Cl. 15	Cl. 18	Cl. 19

New Claims	40	41	42	43	44	45	46	47
Original Support	Cl. 20	Cl. 21	Cl. 22	Cl. 23	Figs. 1-6; pg. 3, ln. 14-16; pg. 5, ln. 9-10	Cl. 9,10,15	Cl. 9,10,18,19	Cl. 9,10,20,22

The claim amendments and the new claims do not introduce any new matter. Entry and consideration of the claim amendments and the new claims are respectfully requested.

4) Referring to sections 1 and 2 on page 2 of the Office Action, the objection to the drawings has been overcome by the present claim amendment.

Claims 17 and 30 reciting the "bayonet lock fastener components" have been canceled without replacement. Thus, the "bayonet lock fastener components" do not need to be shown in the drawings.

Claim 13 originally reciting the "self-locking guide parts" has been canceled, and the related new claim 35 has been corrected to recite that the threading comprises lock threads rather than self-locking guide parts. The lock threads are adequately illustrated by the threadings (3, 8) schematically illustrated in Figs. 3, 5 and 6. A person of ordinary skill in the art is able to understand and provide "lock threads" in various different conventional configurations, whereby such

conventional embodiment features of the lock threads do not need to be illustrated in detail.

For the above reasons, the Examiner is respectfully requested to withdraw the objection to the drawings.

5) Referring to section 8 on page 4 of the Office Action, the indication of allowable subject matter in prior claims 11 to 16, 19, 22, 26 and 28 to 30 is appreciated. It is also noted that claims 18, 20 and 23 have not been expressly rejected on prior art grounds. The allowable subject matter has been incorporated into the present independent claims, as follows.

Independent claim 24 has been amended to incorporate the allowable combination of subject matter of prior claims 24 and 26. Thus, claim 24 and its dependent claim 25 should now be allowable.

Independent claim 27 has been amended to incorporate the allowable combination of subject matter of prior claims 27 and 28. Thus, claim 27 and its dependent claims 29 and 31 should now be allowable.

New independent claim 45 is based on the allowable combination of prior claims 9, 10 and 15, and should be allowable.

New independent claim 46 is based on the allowable combination of prior claims 9, 10, 18 and 19, and should be allowable.

New independent claim 47 is based on the allowable combination of prior claims 9, 10, 20 and 22, and should be allowable.

New independent claim 32 is based on a combination of original claims 9 and 10 with further features that were common to the original allowable claims 11, 12, 16 and 26. Namely, new independent claim 32 now recites that the adapter body has a first threading, the receiver body has a second threading, and these first and second threadings are configured and adapted to be threadingly engaged with each other so as to connect the adapter body with the receiver body. These features are similar to those of original claim 26, and also refer to the threadings provided on the adapter body and the receiver body like in original claims 11, 12 and 16. It is thus submitted that new independent claim 32 should be recognized as allowable, further for the reasons that will be discussed below in comparison to the prior art. Thus, claim 32 and its dependent claims 33 to 44 should now also be allowable.

- 6) Referring to section 4 on pages 2 to 3 of the Office Action, the rejection of claims 9, 10, 24 and 27 as anticipated by U. S. Patent 4,705,516 (Barone et al.) is respectfully traversed in connection with the present amended and new claims.
- 7) As discussed above, present independent claims 24, 27, 45, 46 and 47 each incorporate allowable subject matter from prior claims that had not been rejected. Thus, claims 24, 25, 27, 29, 31, and 45 to 47 are not subject to the present rejection.
- 8) New independent claim 32 incorporates subject matter from prior claims 9 and 10, as well as features from claims 11, 12, 16 and

26 regarding a first threading on the adapter body and a second threading on the receiver body, whereby the two components can be threadingly engaged with each other. These features patentably distinguish claim 32 over Barone et al. as follows.

9) New independent claim 32 is directed to a system for inserting an implant into a human organ.

The main purpose of the new system is to minimize or totally avoid direct touching and handling of the implant (e.g. a heart valve) itself during the implantation procedure (see e.g. page 1, line 17 to page 2, line 12 of the original specification). This is especially important for an implant of biological material such as a biological heart valve, or an implant coated with living cells. Any direct touching or handling of such an implant during the implantation procedure would disrupt or even destroy the coating of living cells or the implant itself.

In order to avoid the direct touching or handling of the implant during the implantation procedure, and instead achieve a "no touch technique" for implanting the implant, the invention provides two separate components that can be connected to each other. Particularly, a receiver element is connected to the recipient organ, and an adapter element carries the implant. For example, a heart valve (as the implant) has been previously sutured to the adapter element in a prior procedure outside of and away from the recipient body. In view of improved accessibility and controllable conditions and the like, it is much easier to suture the heart valve to the adapter element in such a prior procedure outside of the recipient body, than it

would be to suture or otherwise install the heart valve directly into a sewing ring or the like in the recipient body. Also, after the heart valve has been sutured to the adapter element, it can then be coated with a coating layer of living cells. Then, after the living cell layer has been deposited or grown on the heart valve and the adapter element, there is no further need to touch or handle the heart valve itself (which would disrupt the coating layer of living cells), because instead only the adapter element needs to be touched.

Once the adapter element carrying the heart valve has been prepared in the above manner, and the receiver element has been connected (e.g. sutured) to the recipient heart, then it is a quick and simple procedure during the implantation operation to screw or threadingly engage the adapter element (carrying the heart valve) into or onto the receiver element. This procedure can be carried out entirely without directly touching the heart valve itself because only the adapter element needs to be touched or manipulated.

Particularly to achieve the above objects and advantages, claim 32 recites that the present inventive system includes an adapter element comprising a ring-shaped adapter body with a first threading and an annular adapter flange projecting from the adapter body, as well as a receiver element comprising a ring-shaped receiver body with a second threading and an annular receiver flange projecting from the receiver body. The adapter flange is adapted to be connected to the implant (such as a heart valve), the receiver flange is adapted to be connected to the human organ (such as a heart), and the two threadings of the

adapter body and the receiver body are configured and adapted to be screwed or threadingly engaged with each other so as to connect the adapter body with the receiver body.

This combination of features of new independent claim 32 is not disclosed, and would not have been suggested by Barone et al.

10) Barone et al. disclose a system for installing a cardiac valve in a heart.

The system according to Barone et al. includes an adapter element (b', 22) for receiving and carrying a heart valve (c), as well as a receiver element (b, 20) that is to be sutured to a human heart around a blood passage opening thereof, as identified by the Examiner. However, there are significant differences between the construction and arrangement of these components according to Barone et al. in comparison to the present invention.

According to Barone et al., the receiver element or outside collar member (b, 20) is sutured to the heart, and the adapter element or inside collar member (b', 22) is snapped into place in the outer collar member (b, 20) (col. 3, lines 1 to 28). There is NO suggestion that the inside and outside collar members (20, 22) should be provided with respective threadings so as to threadingly engage the two collar members with each other. To the contrary, Barone et al. expressly require the inner collar member to be snapped into place inside the outer collar member.

Furthermore, the heart valve (c) is snapped or screwed into place in the tubular body (32) of the inner collar member (b', 22), whereby it is necessary to physically touch the heart valve

if it is snapped or screwed into place in the inner collar member during the operation procedure. In any event, such direct touching of the heart valve is to be avoided by the present invention. Also, the adapter element (b', 22) according to Barone et al. thus does not have a projecting annular flange that is adapted to be connected to the heart valve (c), but rather the heart valve is snapped or screwed directly into the ring-shaped or tubular body (32) of the adapter element (b', 22). Instead, the annular flanges (30, 34) of the adapter element (b', 22) are engaged with the receiver element (b, 20) for snap-connecting the adapter element to the receiver element.

For the above reasons, present independent claim 32 is not anticipated by Barone et al. Moreover, the invention of claim 32 would not have been obvious from Barone et al., because the reference expressly requires the inner collar member to have a circumferential flange (30) that is "snapped" or captured in a bottom recess (36) of the outside collar member so as to connect the two collar members to each other (col. 3, lines 22 to 28). Such teachings are directly contrary to the inventive features of the threaded connection between the adapter element and the receiver element, and the projecting annular flange of the adapter element for connecting the heart valve thereto. A person of ordinary skill in the art would not have been motivated or enabled to proceed directly contrary to the express teachings of the reference.

The dependent claims 33 to 44 are also patentably distinguishable over Barone et al., already at least in view of their dependence from claim 32. Also, several of these new

dependent claims are based on previously indicated allowable subject matter. Namely, claims 33 to 37 are respectively based on the allowable subject matter of prior claims 11 to 15, claim 39 is based on the allowable subject matter of prior claim 19, and claim 42 is based on the allowable subject matter of prior claim 22.

11) For the above reasons, the Examiner is respectfully requested to withdraw the rejection applying Barone et al. under 35 U.S.C. §102.

12) Referring to section 6 on page 3 of the Office Action, the rejection of claim 17 as obvious over Barone et al. in view of U. S. Patent 6,074,418 (Buchanan et al.) has been obviated.

Original claim 17 has been canceled without replacement. The present remaining claims no longer include the feature of a bayonet lock fastener, for which the Examiner had cited the Buchanan et al. reference. In view of the present amendments, this is no longer relevant.

Furthermore, it is noted that Buchanan et al. also disclose an arrangement including an inner ring (12) that snaps into place in an outer ring (14) that is secured to the human organ. Such an arrangement is purposely provided to avoid loosening or unscrewing of a screwed connection as disclosed by Barone et al., as well as other problems, so that Buchanan et al. expressly and purposely provide a "snap fit" (see col. 1, line 42 to col. 2, line 13). If such teachings had been considered in connection with the above discussed teachings of Barone et al., there would

have been no suggestion toward, but rather a strong suggestion away from the presently claimed inventive system.

For these reasons, the Examiner is respectfully requested to withdraw the rejection applying Barone et al. in view of Buchanan et al. under 35 U.S.C. §103.

13) Referring to section 7 on pages 3 to 4 of the Office Action, the rejection of claims 21, 25 and 31 as obvious over Barone et al. in view of U. S. Patent 5,628,781 (Williams et al.) is respectfully traversed.

The Barone et al. reference has been discussed above in comparison to present independent claim 32. The Examiner has additionally referred to Williams et al. for a suggestion toward coating a heart valve or the like with endothelial cells.

Claims 25 and 31 respectively depend from independent claims 24 and 27, which have now been amended to incorporate allowable subject matter as discussed above. Thus, claims 25 and 31 are allowable in view of their dependence from claims 24 and 27.

Prior claim 21 has been canceled, but similar subject matter is now included in claim 41, depending from claim 32. Williams et al. provide no further suggestions toward the structural arrangement of the components of the system defined in independent claim 32 as discussed above. Thus, claim 41 is allowable already in view of its dependence from claim 32. Furthermore, even if Williams et al. would have suggested coating the heart valve or implant itself with living cells before its implantation, this would not have suggested to cover both the adapter element and the implant with living cells as presently

claimed, because the references would not have suggested the present adapter element in the first place, as discussed above.

For these reasons, the Examiner is respectfully requested to withdraw the rejection applying Barone et al. in view of Williams et al. under 35 U.S.C. §103.

14) Referring to section 9 on page 4 of the Office Action, the additional prior art made of record requires no particular comments because it has not been applied against the claims. In general it is noted that the additional references involve snap-fit type connections and sutured connections between components for implanting heart valves and the like, and do not suggest the presently claimed inventive combinations of features.

15) Favorable reconsideration and allowance of the application, including all present claims 24, 25, 27, 29, and 31 to 47, are respectfully requested.

Respectfully submitted,
Oliver ROEHE et al.
 Applicant

By 
 Walter F. Fasse
 Patent Attorney
 Reg. No.: 36132
 Tel. 207-862-4671
 Fax. 207-862-4681
 P. O. Box 726
 Hampden, ME 04444-0726

WFF:ar/4278/PCT
 Enclosures: Form PTO-2038

CERTIFICATE OF FAX TRANSMISSION:

I hereby certify that this correspondence with all indicated enclosures is being transmitted by telefax to (703) 872-9302 on the date indicated below, and is addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Name: Walter F. Fasse Date: 7/22/03
 4278/WFF:ar

RECEIVED
 CENTRAL FAX CENTER
 SEP 30 2003